IN THE UNITED STATES COURT OF FEDERAL CLAIMS OFFICE OF SPECIAL MASTERS

No. 05-266V Filed: December 19, 2013 Not for Publication

BOB and CARMEL MOONEY, parents *
of E.L.M., a minor child, *
Petitioners, *
v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, Respondent. *

Autism; Petitioners' Motion for Ruling on the Record; Lack of Factual Predicate for a Table Encephalopathy Claim *

Michael Cave, Esq., Cave Law Firm, Baton Rouge, LA, for petitioners. Alexis Babcock, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Chief Special Master:

On August 29, 2013, petitioners filed a motion for a decision on the record. For the reasons set forth below, petitioners have failed to establish entitlement to an award, and thus this case is dismissed.

I. Procedural History.

On February 28, 2005, Bob and Carmel Mooney ["Mr. Mooney," "Mrs. Mooney," or "petitioners"] filed a short-form petition, authorized by Autism General Order # 1,² for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C.

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of that provision, I will delete such material from public access.

² The text of Autism General Order #1 can be found at http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002).

§ 300aa-10, et seq.³ [the "Vaccine Act" or "Program"], on behalf of their minor daughter, E.L.M.

By filing a short-form petition, petitioners joined the Omnibus Autism Program ["OAP"],⁴ thereby asserting that E.L.M. had an autism spectrum disorder ["ASD"] and that one or more vaccines listed on the Vaccine Injury Table⁵ were causal of this condition. The theories of causation eventually litigated in the OAP were that the measles, mumps, and rubella ["MMR"] vaccine, acting alone or in combination with a mercury-based vaccine preservative (thimerosal), caused autism [the "MMR theory" or "Theory 1"] or that thimerosal-containing vaccines [the "TCV theory" or "Theory 2"] were causal. After the conclusion of the appellate process in the OAP test cases, petitioners switched gears and filed an amended petition that alleged E.L.M. had suffered a Table encephalopathy after her 15-month vaccinations.⁶ Amended Petition, filed July 18, 2011.

During an August 18, 2011 status conference, I noted that the filed records did not appear to support a Table encephalopathy claim and suggested that petitioners reexamine their theory of causation. Given the nature of the conflicts between petitioners' joint affidavit and the contemporaneous records (medical records and Mrs. Mooney's own journal⁷), I expressed doubt about whether petitioners had a reasonable basis for pursuing a Table injury claim. In particular, I noted that no encephalopathy and no symptoms such as her parents described in their affidavit were discussed during

³ National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

⁴ The OAP is discussed in detail in *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁵ 42 C.F.R. § 100.3 (2011).

⁶ What constitutes a "Table encephalopathy" is discussed in more detail in Section IV, but the requirements are set forth in the Qualifications and Aids to Interpretation ["QAI"] section of 42 C.F.R. § 100.3. Autism Gen. Order #1 indicated that those petitioners who were alleging Table encephalopathy claims could proceed to hearing on their claims without waiting for the conclusion of the OAP, which contemplated future hearings on causation in fact cases. Autism Gen. Order #1 at 7-8. For reasons not clear from the records, petitioners apparently decided to wait until the test cases were tried and decided before asserting their Table encephalopathy claim.

⁷ Mrs. Mooney maintained a journal to document milestones, family outings, memories, and her general reflections as E.L.M. grew up. She intended to give the journal to E.L.M. when she was older. Transcript from July 26, 2012 hearing ["Tr."] at 48-49. This journal was originally filed on October 17, 2011 as Petitioners' Exhibit ["Pet. Ex."] 10. Petitioners later refiled it as Pet. Ex. 22.

several medical visits⁸ in the six months following E.L.M.'s June 5, 2003 vaccinations. Additionally, Mrs. Mooney's journal, which described other significant events, illnesses, concerns, and achievements, failed to record the dramatic changes in E.L.M. that petitioners now claim occurred shortly after her June 2003 vaccinations. See Order, issued Aug. 18, 2011, at 1; see also § 13(a)(1) (prohibiting a special master from finding entitlement to compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion").⁹

On April 13, 2012, petitioners filed a second amended petition [hereinafter "Petition"], which now constitutes the operative petition for this vaccine injury claim. It is virtually identical to the first amended petition, and alleges only the Table injury claim of encephalopathy within 72 hours of the vaccinations administered on June 5, 2003. Petition, ¶¶ 1f-i, 6. The petition identifies the diphtheria, tetanus, and pertussis ["DTaP"], hepatitis B, haemophilus influenza type B ["Hib"], and pneumococcal vaccines administered on June 5, 2003 as causal. Petition, ¶ 1h. However, encephalopathy is an injury appearing on the Table only with regard to one of these vaccines, the DTaP vaccine, therefore references to the "allegedly causal vaccine" throughout this decision are to the DTaP vaccine alone. 11

In March 2012, petitioners requested a hearing to resolve the factual disputes regarding their Table claim. The hearing was conducted in Sacramento, CA, on July 26, 2012. On July 3, 2013, I issued a combined Ruling on Facts and Order to Show

⁸ In the six month period after the June 5, 2003 vaccinations, E.L.M. was seen once in the emergency room and several times by her pediatrician for both well and sick child visits.

⁹ Although § 13(b)(2) permits a special master to find that the first symptom of a vaccine injury occurred during the period required by the Vaccine Injury Table for a Table injury even if the symptom was not recorded or a record incorrectly reflects that it occurred outside the period, I note that decisions in vaccine cases tend to rely more heavily on contemporaneous medical records rather than testimony or affidavits made months or years after the events in question. *See Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health care professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium."); *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later"); *Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citation omitted) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.").

¹⁰ The petitions differ only in their inclusion and labeling of petitioners' exhibits. The substantive paragraphs of the petitions are identical.

¹¹ Petitioners' claim that the hepatitis B, Hib, and pneumococcal vaccines caused a Table encephalopathy were dismissed as a matter of law in my Ruling on Facts and Order to Show Cause. Ruling, issued July 3, 2013, at 3.

Cause, in which I determined that the evidence failed to establish that E.L.M. suffered a Table encephalopathy and ordered petitioners to show cause by August 2, 2013, why I should not dismiss this case for a failure to establish entitlement to compensation.

On July 22, 2013, petitioners filed a response to my show cause order in which their counsel conveyed their strong disagreement with my factual findings and requested that the "Court enter what is necessary in order for petitioners to exercise their right to appeal." In her response to petitioners' filing, respondent noted that factual findings do not constitute an appealable decision and recommended that I issue a renewed show cause order or dismiss the case for failure to prosecute. See Respondent's Response, filed Aug. 12, 2013. On August 29, 2013, in response to my order instructing them to file a supplemental show cause response, petitioners filed a motion for a decision on the record. Order, issued Aug. 12, 2013; Motion, filed Aug. 29, 2013.

II. Summary of Relevant Medical Records and Other Filed Exhibits.

Petitioners filed twenty-five exhibits in this case. Included in the exhibits are copies of a journal kept by Mrs. Mooney from E.L.M.'s birth in February 2002 to July 2007¹² and home videos of E.L.M. recorded from March 2002 to January 2005. Petitioners also filed several photographs of E.L.M. from before and after the allegedly causal vaccination. *See infra* notes 31 and 51.

Although petitioners had filed a binder containing exhibits 1-9 on June 12, 2009, the first amended petition referred to exhibits 2a-j, and the second amended petition lists exhibits 2-20. Based on these inconsistencies, I reassigned exhibit numbers to all of petitioners' exhibits. References to petitioners' exhibits in this decision are made using the exhibit designations set forth in my April 19, 2012 Order.

Petitioners' Exhibit 23 contains home videos saved as two files "[E.L.M.] Tape 1 of 2 Master" and "[E.L.M.] Tape 2 of 2 Master." In this decision, "tape 1 of 2" will be referenced as Pet. Ex. 23.1 and "tape 2 of 2" will be cited as Pet. Ex. 23.2. Together the two files on the DVD consist of approximately three hours of recordings of E.L.M.

¹² As I commented in my factual ruling, the journal is heartbreaking. The early entries describe a beautiful, engaging, and much loved infant and toddler. Although Mrs. Mooney documents that E.L.M. walked late (Pet. Ex. 22 at 10), displayed some fussiness and high pitched screaming as early as May, 2003 (*id.*), and slowly developed language (*see, e.g., id.* at 11), her love for E.L.M. and her pride and joy in her actions and achievements are evident on every page. Her entry on March 30, 2004, is the first record reflecting her fear that E.L.M. might be autistic. *Id.* at 12. The entries between this one and E.L.M.'s diagnosis with autism on November 30, 2004, reflect her growing concerns about E.L.M.'s behavior. *See id.* at 12-15. The remaining entries describe the whirlwind of treatment options explored and the ups and downs of E.L.M.'s language use, interactions with others, and increasingly more difficult behavior, culminating in her placement in Elk Grove Home for Children, a 24 hour care facility, on July 17, 2007. *Id.* at 15-19; see Tr. at 6-7 (testimony about placement).

and occasionally her sister. Although petitioners identified the recordings as an exhibit they intended to use at the July 26, 2012 hearing (see Petitioners' Status Report, filed July 9, 2012), no excerpts of the exhibit were played at the hearing.

A. First Year of Life (February 2002 – February 2003).

E.L.M. was born on February 11, 2002. She was a healthy newborn, with Apgar scores of 8 and 9.¹³ Pet. Ex. 15, p. 4. She was petitioners' second child;¹⁴ an older sister, F.M., resided in the same family home when E.L.M. was born and throughout E.L.M.'s residence there.¹⁵

During her first year of life, E.L.M. received routine childhood immunizations ¹⁶ and was healthy with no major illnesses. However, she was seen by her pediatrician, Dr. Joyce Bradshaw, for some minor illnesses. In August 2002, E.L.M. experienced a high fever and had possible exposure to leptospirosis. ¹⁷ Doctor Bradshaw sent her to the hospital for antibiotic treatment and testing, which was normal. Pet. Ex. 13, pp. 38-40; see also Pet. Ex. 22 at 8 (Mrs. Mooney's journal entry recording the fever, hospital visit, and tests). A month later, E.L.M. was seen for a crusty eye discharge. She was diagnosed with a likely nasolacrimal duct obstruction, and massage was recommended. Pet. Ex. 13, p. 36. A weight check was also performed at this visit. *Id.*, p. 60; see also Pet. Ex. 22 at 8 (journal entry from September 19, 2002 indicating concern about E.L.M.'s weight). On January 20, 2003, E.L.M. was seen for fever and diarrhea, and was diagnosed with gastroenteritis. In spite of the illness, she was sitting up, alert, playful, and smiling during the visit. Pet. Ex. 13, pp. 58-59. Mrs. Mooney recorded this illness in her journal, noting that E.L.M. had a "bad flu." Pet. Ex. 22 at 9.

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¹³ The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] (32nd ed. 2012) at 1682.

¹⁴ Mrs. Mooney has a third daughter from a prior marriage. Tr. at 68-69.

¹⁵ E.L.M. was placed in a 24 hour care facility on July 17, 2007. Pet. Ex. 5, pp. 10-15; Tr. at 6-7.

¹⁶ On April 22, 2002, E.L.M. received her first vaccinations, which included Prevnar, inactivated polio vaccine ["IPV"], DTaP, and a combined hepatitis B/Hib vaccine. Pet. Ex. 2, pp.1-2. She received the second round of the same vaccinations at her four month well child visit. *Id.* She received her third Prevnar, IPV and DTaP vaccinations at her six month well child visit on August 23, 2002. *Id.*

¹⁷ Leptospirosis is an infection that can be acquired from exposure to pet urine. A family puppy had died recently, and leptospirosis was suspected in the puppy's death. Pet. Ex. 13, p. 38; DORLAND'S at 1024.

Although there were some concerns about her growth, E.L.M.'s development was consistently assessed as normal during this time period. At her six month well child visit on August 23, 2002, Dr. Bradshaw noted E.L.M.'s height-weight ratio was at 10%, and requested that she return for evaluation in one month. She returned on September 18, 2002. Her height-weight ratio was still at 10%. Doctor Bradshaw noted that a "failure to thrive" workup should be considered at nine months if E.L.M.'s pattern of low weight gain continued. At the nine month well child visit on November 26, 2002, her height and weight both remained at the 10th percentile. Although Mrs. Mooney indicated that her older daughter was also small and that she was not concerned about E.L.M.'s weight, Dr. Bradshaw indicated that she would continue to monitor E.L.M.'s weight gain. Pet. Ex. 13, p. 34.

B. February 2003 – June 2003.

E.L.M.'s next well child visit took place on March 3, 2003, when she was not quite 13 months of age. Her growth and development were assessed as normal. E.L.M. was using a cup instead of a bottle, indicating her wants without crying, and had a vocabulary of at least two to three words, but she was not yet walking. Her height and weight had improved, with both at the 20th percentile. Urinalysis showed a trace amount of blood and protein, but there was not enough urine to send for a urine culture. The plan was to repeat the urinalysis. Pet. Ex. 13, p. 34. She received her first MMR and varicella vaccinations at this visit. Pet. Ex. 2, pp. 1-2.

Based on the urinalysis results obtained on March 3, 2003, a repeat urinalysis was performed on March 4, 2003. This testing showed mixed gram positive flora and mixed gram negative rods. Pet. Ex. 13, p. 30. Another sample was ordered on March 5, 2003, which proved difficult to obtain. *Id.*, pp. 30, 33. On March 9, 2003, a urine sample tested positive for bacteria and antibiotics were prescribed to treat this urinary

¹⁸ There is only a computer record, which does not contain the examination notes, for E.L.M.'s two month well child visit. Pet. Ex. 13, pp. 61-62. However, her growth and development were considered normal at her four month well child visit. *Id.*, pp. 37, 61-62. Her development was considered normal at her six month well child visit, but there were concerns about her growth. *Id.*, p. 37. Her development was assessed as normal at her nine month well child visit on November 26, 2002. Pet. Ex. 16, pp. 7, 20. She pulled to stand, sat without support, and made repetitive sounds. *Id.*

¹⁹ On June 13, 2002, E.L.M.'s weight was recorded as 14 lbs, 6 ozs. On August 8, 2002, she weighed 14 lbs, 1 oz, and at her six month well-child visit E.L.M.'s weight was noted to be 14 lbs, 5 oz. Doctor Bradshaw indicated that the June weight was possibly wrong, but wanted an appointment to recheck E.L.M.'s weight. Pet. Ex. 13, p. 37.

²⁰ Pet. Ex. 13, p. 36. Petitioners testified that concerns over E.L.M.'s weight gain and use of the term "failure to thrive" first occurred after her June 5, 2003 immunizations (Tr. at 22, 57-58, 108), but it is clear from the pediatric records that the first concerns about her weight gain and stature occurred at the time of her six month well child visit. There were no medical records reflecting concerns about E.L.M.'s weight after the allegedly causal vaccination.

tract infection. Id., p. 32.

The video records for the four month period between her first birthday (February 11, 2003) and the one closest in time to the June 5, 2003 vaccinations (June 4, 2003) reflects that, as to the periods recorded, E.L.M. frequently failed to respond to her name and occasionally flapped her hands. *See*, *e.g.*, February 19 (Pet. Ex. 23.2 at 25:18), April 22 (Pet. Ex. 23.1 at 1:07:33), May 20 (Pet. Ex. 23.2 at 1:10:58), and May 28, 2003 (Pet. Ex. 23.1 at 1:14:05) (documenting E.L.M.'s failure to respond); February 9 (Pet. Ex. 23.1 at 59:45), February 17 (Pet. Ex. 23.2 at 23:04), and April 1, 2003 (Pet. Ex. 23.1 at 1:04:24) (showing hand flapping). ²¹

C. June 5, 2003.

E.L.M. returned for her next well child visit on June 5, 2003, when she was almost 16 months of age. The developmental screening checklist recorded that she could walk two steps,²² indicate her wants without crying, speak at least two to three words, had pincer grasp, and was using cups. Pet. Ex. 13, p. 29. E.L.M. received the allegedly causal DTaP vaccination (her fourth), plus her fourth Prevnar vaccination at this visit. Pet. Ex. 2, pp. 1-2. Among the teaching topics checked as discussed with Mrs. Mooney was "IZ Reactions," which I interpret as meaning "immunization reactions." Pet. Ex. 13, p. 29.

D. Six Months Following E.L.M.'s June 5, 2003 Vaccinations.

During the six months following her June 5, 2003 vaccinations, E.L.M. was seen by several health care providers. The records reflect a child who interacted with her environment and responded to her parents and caregivers. Mrs. Mooney's journal and petitioners' home videos provide additional insight into E.L.M.'s behavior during the six month period.

The first journal entry after the June 2003 vaccinations is from June 16, 2003. It reflects a significant milestone—E.L.M.'s first unaided steps. The video from the event shows E.L.M. responding to cheers when she walked for the first time. Pet. Ex. 23.1 at

²¹ Based on my experience in many other vaccine injury claims, including the OAP test cases, I am aware that lack of response to name in a toddler is considered an early manifestation of autism. Hand flapping in a toddler may also be a symptom. *Cedillo v. Sec'y, HHS*, No. 98-916V, 2009 WL 331968 at *96-97 (Fed. CI. Spec. Mstr. Feb. 12, 2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010).

²² The checklist contains the skill "Walks" and the evaluator wrote "2 steps" next to this word. Pet. Ex. 13, p. 29. There is other evidence to suggest that E.L.M. was not yet walking, and certainly not walking well. In early May 2003, Mrs. Mooney noted that E.L.M. was "cruising holding onto stuff" and predicted that she would soon be walking. Journal, Pet. Ex. 22, at 10. The journal entry from June 16, 2003, notes that E.L.M. walked for the first time that evening and that Mrs. Mooney caught it on film. *Id.* at 10; see also Pet. Ex. 23.1 at 1:19:21 (the video of E.L.M.'s first steps, as narrated on the video by Mrs. Mooney).

1:19:21. The next two journal entries are dated July 1 and July 24, 2003.²³ In the first of these entries, E.L.M. is briefly described as still preferring crawling to walking, but walking more often. Pet. Ex. 22 at 10. The second reflects that E.L.M. had not "been acting like [herself] lately," but does so in the context of a recurring runny nose for the last few weeks. *Id.* Other entries reflect thumb-sucking, being playful on her mother's lap, and exploring what appears to be either "rocks" or "books," while her older sister took swimming lessons. *Id.* There is no mention of lethargy, aloofness, ²⁴ disinterest in her environment, or any lack of eye contact.

E.L.M. was first seen by a health care provider after the June 5 vaccinations on August 1, 2003, when she was taken to the Dominican Hospital emergency room ["ER"] for vomiting.²⁵ Her parents were asked about her medical history; the record reflects they reported that E.L.M. had not experienced any serious illnesses. Her physical exam was normal, and she was both alert and oriented to her environment. Pet. Ex. 20, pp. 2-4. During one evaluation, she was happy, smiling, and singing while at another she was in tears, but easily consolable, awake, alert, talking, and playful. *Id.*, pp. 2-3. She was diagnosed with vomiting and mild dehydration. *Id.*, p. 3.

E.L.M.'s eighteen month well child visit occurred on September 18, 2003, after a seven day cruise to Alaska. No problems were noted and E.L.M.'s growth and development were recorded as normal. In particular, she was noted to climb into adult chairs, walk well/rarely fall, follow directions, point to body parts, have at least 10-15 words, engage in imitative play, and use a spoon. Pet. Ex. 13, p. 23. The urine analysis was positive for protein and blood, and, given E.L.M.'s prior urinary tract infection, a repeat sample was requested. *Id.* No concerns about E.L.M.'s eye contact or interactions with her caregivers or environment were recorded. Mrs. Mooney's

²³ The journal entries were made periodically, not daily or weekly. They sometimes describe the events of a particular day or summarize events occurring over a period of time between entries.

²⁴ It appears from the medical records and Mrs. Mooney's journal entries that E.L.M.'s pretend play and clear affection for and interaction with her mother played a significant role in the reluctance of several specialists and her primary pediatrician to diagnose her with autism when she was first evaluated. *See, e.g.*, journal entries dated June 5, and September 17, 2004, Pet. Ex. 22 at 12-13; Dr. Bradshaw's July 12, 2004 visit note, Pet. Ex. 13, p. 22 ("We discussed [E.L.M.'s] developmental delay and autism. I do not think that E.L.M. has other diagnostic criteria at this time."); September 23, 2004 Psychological Evaluation, Pet. Ex. 5, p. 8 ("E.L.M. is currently not displaying a significant impairment in social interaction or in communication other than her expressive language usage. No repetitive interests or motor mannerisms are reported. Therefore, she does not meet the criteria for a pervasive developmental disorder diagnosis.").

²⁵ Mrs. Mooney recorded this visit in her journal on August 11, 2003, noting that E.L.M. had picked up "a nasty bug" last week while visiting Santa Cruz. She noted that E.L.M. was 18 months old, and was beginning to "speak [her] mind" in protest. She described E.L.M. as "sweet almost all the time," smiling and giggling, and noted that she clapped her hands. However, she also commented that E.L.M. would fuss and make a high-pitched scream when in stores. Pet. Ex. 22 at 11.

journal entry, dated September 2, 2003, reflected that E.L.M. was as "adorable as always" on the cruise that preceded this well child visit, and that she cooed and smiled on the trip, and appeared to enjoy watching the mountains and whales from the ship. Pet. Ex. 22 at 11; see also Pet. Ex. 23.2 at 31:11 to 33:15 (video taken during the August 2003 vacation).

E.L.M. continued to use new words during this period, as her mother's November 3, 2003 journal entry reflected that she had learned to say "up" and "down." Pet. Ex. 22 at 11. Whether this was true acquisition of words that E.L.M. continued to use was unclear, as a November 20, 2003 entry reflected that E.L.M. was "paying more attention" and was starting to "mimic" language more. *Id.* This last comment may reflect that E.L.M.'s use of new words was echolalia, ²⁶ a condition often seen in autistic children in which words spoken by others are repeated, but not used spontaneously or independently. Mrs. Mooney expressed her hope that E.L.M. might soon learn to "speak English," suggesting that her language skills were lagging. She noted that E.L.M. often became frustrated because she couldn't verbalize. *Id.* This was the last journal entry in the six month period after the June 5, 2003 vaccination.²⁷

The videos during the six month period after June 5, 2003 reflect a toddler who enjoyed playing and taking in new surroundings, and one who smiled and reacted to the presence of others. *See, e.g.*, Pet. Ex. 23.1 at 1:19:21 (reacting to cheers after taking her first unassisted steps on June 16, 2003), 1:20:51 (playing a toy piano with sister F.M. on June 24, 2003), and 1:23:45 (trying to play with F.M.'s ball game on July 2, 2003); Pet. Ex. 23.2 at 31:50 (reacting to Mrs. Mooney joining E.L.M. and Mr. Mooney on deck on August 21, 2003) and 32:26 (responding to Mrs. Mooney's "baby talk" vocalizations on August 24, 2003).

E.L.M. was seen on December 17, 2003 for rhinorrhea and persistent cough for two to three days. According to Mrs. Mooney, E.L.M.'s coughing had been occurring every few seconds, but was now decreased to every few minutes. During the exam, E.L.M. was "playful [and] in no apparent distress." She was diagnosed with an upper respiratory infection with persistent cough. Pet. Ex. 13, p. 26.

²⁶ DORLAND'S at 589.

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²⁷ The next journal entry also reflected E.L.M.'s frustration at being unable to communicate verbally. It was dated on March 9, 2004, more than three months after the previous entry. Pet. Ex. 22 at 12. The following entry, dated March 30, 2004, reflected Mrs. Mooney's first recorded concern that something was wrong with E.L.M.'s behavior, based on her own internet research and concerns expressed by E.L.M.'s babysitter. One of the concerning behaviors was E.L.M.'s failure to follow commands. *Id.* at 12. This problem with receptive language is frequently observed in autistic children. *See Cedillo*, 2009 WL 331968 at *96-97.

III. Summary of Petitioners' Testimony.

At the July 26, 2012 hearing, both Mr. and Mrs. Mooney testified as to the reaction and changes they observed in E.L.M. immediately following her June 5, 2003 vaccinations and over the ensuing six month period.

A. Immediate Reaction to June 5, 2003 Vaccination.

E.L.M.'s parents provided similar descriptions of the events in the 72 hours after her June 5 vaccinations. They testified that between accompanying her mother on errands and the doctor visit that Thursday, E.L.M. was more tired than usual so she was put to bed a little earlier than her usual bedtime of 8:00 pm. Tr. at 11, 88-89. The morning of Friday, June 6 began like any other morning, with petitioners having coffee and breakfast on their deck. Around 9:00 am, petitioners became concerned that E.L.M. was not awake yet, as she typically woke up between 7:00 and 8:00 am. Tr. at 11-12, 89. Mrs. Mooney went up to check on her, did a visual inspection, and saw that E.L.M. was still sleeping. Tr. at 12, 89. Petitioners assumed E.L.M. was not feeling well and needed extra sleep. Tr. at 12.

Around 10:00 am, both Mr. and Mrs. Mooney checked on E.L.M., who was still asleep. Tr. at 12-13, 89. They pulled back her blankets and noticed that she was hot and sweaty. Mrs. Mooney testified that she was very concerned and tried to wake E.L.M. E.L.M. usually would greet her mom in the morning by leaning against the crib's railing and lifting her arms up, anticipating being picked up. However, when Mrs. Mooney tried to wake her, E.L.M. was "very groggy and unresponsive." Tr. at 13-14. Both parents recall Mrs. Mooney taking E.L.M.'s temperature, but neither remembered the numerical temperature reading. Tr. at 13, 90, 104-05. Mrs. Mooney then called the pediatrician's office and was told to give E.L.M. some Tylenol and that the symptoms she was exhibiting were common reactions to vaccines. Tr. at 13, 90. E.L.M. slept again after being given Tylenol. Tr. at 13

When E.L.M. woke up for the second time³⁰ she seemed to be lethargic and not as energetic or alert as she usually was. According to Mr. Mooney, E.L.M. appeared to be in a daze and not completely conscious. Tr. at 97. She spent some of the afternoon being held by her parents on the couch before being put to bed around her normal

²⁸ Mrs. Mooney described her as "very hot and sweaty," while Mr. Mooney conveyed she was "sweating a little bit" and "a little hot" and her cheeks were "a little red, redder than normal." Tr. at 13, 90.

²⁹ Video recorded on March 28, 2003 shows E.L.M. waking up from a nap in the manner described as typical by Mrs. Mooney. Pet. Ex. 23.1 at 1:03:46.

³⁰ Mrs. Mooney's testimony implied that E.L.M. woke up on her own, while Mr. Mooney testified that they had to wake her up. See Tr. at 13, 91.

bedtime. Tr. at 13-14, 91, 106. According to Mrs. Mooney, E.L.M. acted like she didn't feel well. She did not "want to eat very much. She wasn't her normal self." Tr. at 15.

Mr. Mooney testified that he could not recall any specifics about E.L.M.'s behavior on June 7 and June 8 (Tr. at 91), but also testified that he distinctively remembered E.L.M. appearing "very different" in her high chair at dinner on one of those nights. Tr. at 107. She was sitting up in the highchair, not lolling around in it, but seemed different in the manner she was eating and reacting to her sister. *Id.* Mrs. Mooney noted that in the days immediately following the vaccinations, E.L.M. seemed like she felt unwell, was not very responsive, lacked good eye contact, and did not speak. Tr. at 15. E.L.M. also was very fussy and cried a lot. *Id.*

According to Mrs. Mooney's testimony, the time from Thursday night to Friday morning "was the most concerning strange change in her normal behavior." Tr. at 15. The rest of the weekend, she didn't seem like she felt well. She was not very responsive, didn't "give us very good eye contact and didn't speak at all." *Id.*

Mr. Mooney indicated that they initially thought E.L.M. was "fighting some type of . . . cold, flu, infection, some type of sickness," although he admitted that he did not pay too much attention to it. Tr. at 91. He stated that he does not remember anything specifically unusual about her behavior and agreed that if E.L.M. was acting abnormal it was not grossly abnormal. Tr. at 106-07.

B. Six Months Following the June 5, 2003 Vaccinations.

Mrs. Mooney commented that "[w]hen a child gets sick usually they, within a couple of days, typically, they start to seem like them-theirselves again. [E.L.M.] never came back to what we had observed as being normal for her again. So when she got rid of the fever, she still continued to be unhappy and not give us good eye contact and not interact the normal way she had before with us and she seemed very detached from her environment." Tr. at 16.

Social Interaction.

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Mr. and Mrs. Mooney both testified that after the June 5, 2003 vaccinations, E.L.M. would not follow instructions or short commands, such as "come here," "sit down," or "bring the ball." See Tr. at 26, 97. They also reported that E.L.M.'s eye contact changed. It was very difficult for them to get a reaction, such as when they tried getting her to look at a camera or smile for a photograph. Tr. at 26-28, 97. Petitioners filed a series of photographs, many allegedly taken after the 15 month vaccinations, 31

³¹ Most of the photographs include handwritten notes identifying what event or activity is depicted, and for some the date of the activity. It is not clear when the notes were written or who wrote the notes. See Tr. at 68-69. Since most of the photographs do not have a camera-generated date stamp, the handwritten notes and petitioners' testimony must be relied upon to determine when the photograph was taken. For

reflecting E.L.M. looking away from the camera. Pet. Ex. 21; see also Tr. at 31-48, 94-96 (testimony regarding the photographs).

Petitioners also discussed a change in E.L.M.'s play after the vaccinations. Prior to June 5, 2003, she enjoyed playing with dolls, her sister's dollhouse, trucks and other wheeled toys, and rolling around with the family dog. Tr. at 21, 26-28, 87. She also enjoyed climbing into people's laps, bath time, and playing pat-a-cake. *Id.* E.L.M. was very responsive to childhood television programs and showed "a lot of imaginary play and interaction with her sister and her sister's friends." Tr. at 21. According to petitioners, all of these activities and behaviors diminished or disappeared after her vaccinations. Tr. at 27-28, 92-94.

2. Speech and Language Development.

Mrs. Mooney testified that E.L.M. spoke around 10 to 15 words and was slowly gaining new vocabulary prior to the June 5, 2003 vaccinations. Tr. at 8-9. After the vaccinations, E.L.M. did not speak at all for a while and when she began speaking again, would only rarely use new words. Tr. at 21.

3. Constant Screaming and Crying.

Mrs. Mooney testified that, prior to receiving the June 2003 vaccinations, E.L.M. was a very easy-going, good-natured baby. Tr. at 16. She fussed and cried less than her siblings had. *Id.* After the vaccinations, Mrs. Mooney testified that they were unable to console or quiet E.L.M.. *Id.* E.L.M.'s crying was not normal, standard child crying, but according to Mrs. Mooney was "high-pitched shrieking, deafening screaming" that "increased in intensity and increased in frequency to the point that, over the course of about a year, about a year from [June 5] she was screaming several hours per day with high, shrieking, screaming intensity. And by the time she was three or four it was many hours per day." Tr. 17-18.

Mr. Mooney also indicated that E.L.M. was previously very easy-going, and that after the vaccines she started to "scream and cry more often." Tr. at 92. He noted that her screaming got worse over time. Tr. at 93. Petitioners tried various things, such as taking long drives with E.L.M. in the car, playing music, rocking her, and putting her in her swing, but according to Mrs. Mooney nothing seemed to soothe her. Tr. at 16-17. Mr. Mooney indicated that it was possible to console her, but it took a lot more time than before the vaccines to do so. Tr. at 92.

at least one photograph it appears that the handwritten date is incorrect. Photograph 22 is labeled as "12 months old – Happy," and depicts E.L.M. in a highchair enjoying an ice cream cone. Pet. Ex. 21 at 22; see also Tr. at 38. However, according to petitioners' video recording, E.L.M.'s first ice cream cone occurred on June 27, 2003, when she was 16 months of age. Pet. Ex. 23.1 at 1:21:20. E.L.M. is wearing the same dress in the photograph and video recording, making it likely that both images were captured on the same day.

4. Appetite and Weight Gain.

Mrs. Mooney explained that E.L.M. did not want to eat in the first few days after the vaccinations, but then her eating returned to its normal level. Tr. at 20, 29. According to Mrs. Mooney, after receiving the vaccines E.L.M.'s growth and weight dropped to the 10 or 20th percentile and she did not gain weight as she had before. She indicated that the pediatrician referred to this as a failure to thrive. Tr. at 22, 57-58.

IV. Discussion of Petitioners' Causation Theory.

Under the Vaccine Act, the petitioner bears the burden of proving a vaccine-caused injury. There are two ways causation may be demonstrated. First, a petitioner may establish a "Table" injury. Alternatively, a petitioner may prove that a vaccine listed on the Table actually caused or significantly aggravated an injury (an "off-Table" injury). In this case, petitioners allege that E.L.M. suffered a Table encephalopathy following her DTaP vaccination on June 5, 2003.

A. Legal Standard.

To establish their Table encephalopathy claim, petitioners must demonstrate that E.L.M. manifested an injury encompassed in the definition of an acute encephalopathy within 72 hours of her vaccination and that a chronic encephalopathy was present for more than 6 months after the acute encephalopathy. 42 C.F.R. § 100.3(b)(2).³⁴

For a child younger than 18 months, presenting without an associated seizure event, an acute encephalopathy is indicated "by a significantly decreased level of consciousness . . . lasting for at least 24 hours." § 100.3(b)(2)(i)(A). A significantly decreased level of consciousness is demonstrated by the presence of one of three clinical signs for a period of at least 24 hours: "(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things)." § 100.3(b)(2)(i)(D). Sleepiness, irritability (fussiness), high-pitched and

³³ The questions asked during the redirect examination of Mrs. Mooney by petitioners' counsel (see Tr. at 75-79) appear to suggest that petitioners were exploring a mitochondrial disorder-based causation theory, but petitioners did not allege any causation-in-fact theory in their second amended petition or in response to my Order to Show Cause.

³² See § 11(c)(1)(C); 42 C.F.R. § 100.3 (2010).

³⁴ The QAI section of the Vaccine Injury Table, 42 C.F.R. § 100.3(b), contains definitions for the terms used in the Table. *See Althen v. Sec'y, HHS*, 58 Fed. Cl. 270, 280 (2005), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005) (noting that the QAI should be used to interpret key terms found in the Table).

unusual screaming, persistent inconsolable crying, and bulging fontanelle are not, alone, or in combination, a demonstration of an acute encephalopathy. § 100.3(b)(2)(E). An acute encephalopathy is an event "that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)."

A chronic encephalopathy is defined in the QAI as "a change in mental or neurologic status, first manifested during the applicable time period, [that] persists for a period of at least 6 months from the date of vaccination." § 100.3(b)(2)(ii). If a person returns to a typical neurologic state after suffering an acute encephalopathy, they are not presumed to have suffered residual neurologic damage and "any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy." *Id.*

The clinical signs and symptoms of an encephalopathy were incorporated ³⁶ into the QAI to "clearly distinguish infants and children with brain dysfunction from those with transient 'lethargy.'" Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7687. As noted in *Waddell*, by then Chief Special Master Campbell-Smith, ³⁷ the QAI definition of significantly decreased level of consciousness implies "a state of diminished alertness that is much more than mere sleepiness or inattentiveness . . . [it] requires markedly impaired - or strikingly absent - responsiveness to environmental or external stimuli for a sustained period of at least twenty-four hours." *Waddell v. Sec'y, HHS*, No. 10-316V, 2012 WL 4829291, at *7 (Fed. CI. Spec. Mstr. Sept. 19, 2012).

The revised QAI definition aimed to differentiate between the "diminished alertness and motor activity [] which characterize [a] lethargic infant or child" and the "more serious impairment of consciousness that is the hallmark of encephalopathy (i.e., obtundation, stupor and coma)." Revision of the Vaccine Injury Table, 60 Fed. Reg. at

³⁵ § 100.3(b)(2)(i). When revising the QAI definition it was noted that the hospitalization requirement was not intended "as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event." Revision of the Vaccine Injury Table, 60 Fed. Reg. 7685, 7687 (Fed.

20, 1997) (preamble to final rule).

The original definition of encephalopathy was: "any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram." § 14(b)(3)(A).

³⁷ On September 19, 2013, Chief Special Master Campbell-Smith was appointed Judge of the U.S. Court of Federal Claims. On October 21, 2013, Judge Campbell-Smith was designated as the Chief Judge of the U.S. Court of Federal Claims.

7687; see also Romano v. Sec'y, HHS, No. 90-1423, 1993 WL 472879, at *6 (Fed. Cl. Spec. Mstr. Nov. 1, 1993) (citing Gerald Fenichel, CLINICAL PEDIATRIC NEUROLOGY (1st ed. 1988) at 42) ("Among the altered states of consciousness associated with an encephalopathy are states of: (1) increased consciousness, which can present as delirium; and (2) decreased consciousness, which can present as lethargy, obtundation, stupor, or coma."). Dramatic or severe symptoms must be present to meet the Table encephalopathy definition.³⁸

B. Analysis of Petitioners' Table Claim.

The evidence fails to establish that E.L.M. suffered from an acute encephalopathy within 72 hours of her June 5, 2003 DTaP vaccination. Assuming, arguendo, that she did have an acute encephalopathy, there is insufficient evidence to demonstrate that E.L.M. exhibited symptoms of a chronic encephalopathy for the six months following her DTaP vaccine, and ample evidence that she did not.

As I noted in my fact ruling, I do not find sufficient indicia of reliability in the testimony of petitioners to credit their testimony over the evidence found in the contemporaneous records. Their accounts of what occurred following E.L.M.'s June 5, 2003 vaccinations are inconsistent with Mrs. Mooney's journal, as well as inconsistent with observations and statements made in contemporaneous records. Most strikingly, they are inconsistent with videos taken of E.L.M. within a week of the June 5 DTaP vaccination³⁹ and with videos taken in the months that followed. Although it is not unusual for some details to be missing from the contemporaneous records, the specific facts of this case, the improbability of the petitioners' description of events, and Mrs. Mooney's own journal entries make it highly unlikely that their otherwise unsupported accounts are accurate. I also considered the length of time that has passed since the

³⁸ See, e.g., *Jay v. Sec'y, HHS*, 998 F.2d 979, 981, 984 (Fed. Cir. 1993) (noting the Special Master's comment that "[w]ith an encephalopathy we typically seen at least one dramatic aspect. This aspect is what separates the events from the normal range of DTP reactions" and concluding that the "dramatic aspect" in the case was the child's death); *Gamache v. Sec'y, HHS*, 27 Fed. Cl. 639, 642 (1993) (upholding a dismissal decision in which the special master had concluded that "screaming and crying in and of themselves are not conclusive evidence of encephalopathy. [The vacinee's] high-pitched and unusual screaming and inconsolable crying are explainable as a local, systemic reaction to the DPT vaccine rather than as indicia of encephalopathy."); *Watt v. Sec'y, HHS*, No. 99-25V, 2001 WL 166636, at *8 (Fed. Cl. Spec. Mstr. Jan. 26, 2001) (citing expert testimony that the symptoms relied upon to establish a table encephalopathy "cannot merely be crying, it cannot--inconsolable crying; it cannot merely be crankiness; it cannot merely be a number of things.").

³⁹ The first video recording of E.L.M. after the allegedly causal vaccination is dated June 11, 2003, and shows E.L.M. seated in a child's chair sucking her thumb. She initially does not respond to her name, but then turns her face towards the video camera. Pet. Ex. 23.1 at 1:17:23. Two days later, on June 13, 2003, E.L.M. is seen pushing a doll stroller while walking on her knees, trying on sunglasses, and walking while holding on to the doll stroller. *Id.* at 1:17:47. On June 16, 2003, E.L.M. walks unassisted for the first time. *Id.* at 1:19:21.

events in question to be an important consideration when evaluating the accuracy of their recollections.

1. Acute Encephalopathy.

There were no videos submitted that capture E.L.M.'s behavior and functioning in the first 72 hours following her June 5, 2003 DTaP vaccination, no reports in contemporaneous records, ⁴⁰ no journal entries, and no histories that reflect the matters to which petitioners testified and set forth in their affidavit. ⁴¹ E.L.M. may have had a temporary, noticeable change in behavior, such as a fever and appearing more tired than usual, after she received her 15 month vaccinations, but there is insufficient proof that she had the dramatic behavior changes after her vaccinations required to meet the Table definition of an "acute encephalopathy."

Even if the Vaccine Act did not preclude me from relying on petitioners' claims alone, "unsubstantiated by medical records or medical opinion" (see § 13(a)(1)), there exist many other reasons for rejecting their testimony about the initial vaccine reaction. For example, petitioners routinely scheduled appointments with E.L.M.'s pediatrician when she was ill (see, e.g., Pet. Ex. 13, pp. 8, 26, 35-36) and they were willing to take her to an emergency room for treatment (Pet. Ex. 20, pp. 2-3), but petitioners did not take E.L.M. to a medical professional for nearly two months after her June 5, 2003 vaccinations. If her symptoms and behavioral changes were as immediate and severe as petitioners allege they were, I believe petitioners would have sought medical

⁴⁰ Petitioners allege they called E.L.M.'s pediatrician in the week following her vaccinations (Tr. at 13, 90), but there is no notation of a phone call in the Auburn Bell Pediatrics records. The records do include documentation of several phone calls between petitioners and Dr. Bradshaw that took place in January 2005. *See* Pet. Ex. 17, p. 7.

⁴¹ In their affidavit, signed and filed in July, 2011, petitioners stated that "[t]he day [E.L.M.] got the vaccines, she got [a] high fever, went to sleep, and would not wake up for 15 or 16 [hours]. When she did wake up, she would not look at [them] or speak." Pet. Ex. 1 at 2. Within seventy-two hours of her vaccinations, [E.L.M.] "became withdrawn, disinterested in her environment, unable or unwilling to look at her family members. She failed and refused to interact with her family members in a normal way, had a significantly diminished or absent response to her environment, had other unusual and inappropriate responses to her environment and showed general withdrawal." *Id.*

⁴² The first post vaccination medical record is from August 1, 2003, when petitioners took E.L.M. to the Dominican Hospital emergency room for vomiting. Pet. Ex. 20, pp. 2-3; see also Journal, Pet. Ex. 22, at 11. She did not return to her pediatrician until her eighteen month well child visit on September 18, 2003.

⁴³ I note that petitioners' allegations are not consistent. For example, Mrs. Mooney testified that E.L.M. displayed an immediate reaction to the vaccines, with striking changes in her behavior and interaction with others. Tr. at 27. However, she also testified that after E.L.M.'s initial fever resolved, she "slowly" started "showing less and less and less eye contact and response." Tr. at 54. Mrs. Mooney also testified that "things went quickly downhill" when E.L.M. was around twenty months of age, and agreed that she "first became really concerned with development type of things" in March 2004. Tr. at 61, 66-67.

attention for their child. This reasoning is further buttressed by the entry in E.L.M.'s records concerning a discussion about immunization reactions at the same visit in which the allegedly causal DTaP vaccination was administered.

Additionally, Mrs. Mooney appears to have recorded significant illnesses E.L.M. experienced in her journal. *See, e.g.*, Pet. Ex. 13, pp. 38-40 and Pet. Ex. 22 at 8 (initial ER visit for high fever when seven months old); Pet. Ex. 13, p. 25 and Pet. Ex. 22 at 9 (ER visit for gastroenteritis). No such entry appears in the journal for the week following the allegedly causal vaccine. Although Mrs. Mooney attempted to explain why no entry was made, I did not credit this explanation, in the light of other entries recording negative events or behaviors.⁴⁴

2. Chronic Encephalopathy.

There are sufficient observations and parental reports of milestones achieved in the contemporary records to make it difficult to accept petitioners' more recent assertions about E.L.M.'s symptoms in the six months that followed the June vaccinations. ⁴⁵ Additionally, the medical histories provided during several developmental evaluations, ⁴⁶ as well as updates conveyed to her pediatrician ⁴⁷ in 2004,

⁴⁴ Mrs. Mooney testified that the changes are not described in detail in the journal because she wanted to keep the entries upbeat and positive and therefore did not describe how "bad things really were." Tr. at 49, 66. *But* see Pet. Ex. 22 at 4 (3/13/02 entry noting E.L.M. had been "puking a few times a day for the past few days"), 8 (9/6/02 entry reporting that E.L.M. had started to cry a lot), and 10 (3/26/03 entry documenting E.L.M.'s possible bladder infection and 5/8/03 entry noting that E.L.M. was fussing, screaming a lot and having bad separation anxiety).

⁴⁵ Although I accept Mrs. Mooney's testimony (Tr. at 70) that the ER physician did not spend much time with E.L.M. during the August 1, 2003 visit, the records from the visit reflect that E.L.M. was happy, smiling, and singing at one point, and in tears, but easily consolable, awake, alert, talking, and playful at another point. Pet. Ex. 20, pp. 2-3. Doctor Bradshaw's records from the six month period following the allegedly causal vaccine do not mention any abnormal behavior or lack of responsiveness. Even if I were to accept petitioners' assertion that Dr. Bradshaw did not document the concerns they raised (see Tr. at 57, 70-71), I would still find insufficient support for their contentions concerning E.L.M.'s behavior. The video recordings establish that any behavior changes did not reach the level of impairment required under the statute to establish a chronic encephalopathy.

⁴⁶ E.L.M. saw two different providers for speech and language evaluations in August 2004. Pet. Exs. 3 (Placer Speech & Hearing Services) and 4 (The Speech Works). She was seen by a staff psychologist at the Alta California Regional Center in September 2004. Pet. Ex. 5. In October and November 2004, E.L.M. was seen by personnel at the University of California, Davis M.I.N.D. Institute, Early Developmental Studies Laboratory. Pet. Exs. 6-7. Additionally, in the fall of 2004, she underwent a multivisit occupational therapy evaluation. Pet. Ex. 8.

⁴⁷ In addition to her 2 year well child visit, E.L.M. went to the pediatrician in 2004 for a discussion of the findings of the developmental evaluations and a sick visit for congestion and allergic reaction to amoxicillin. Pet. Ex. 13, pp. 5, 8-9, 20, 22-23, 25, 47-54.

do not support petitioners' contentions.⁴⁸ Furthermore, Mrs. Mooney's own journal casts substantial doubt on their testimony that these behaviors began in close temporal relationship to the June 5, 2003 vaccinations.⁴⁹

The medical records chronicle a relatively typical gradual onset of symptoms concerning to parents and caregivers, followed by parents raising their concerns to a primary care provider, and ultimately referrals to specialists. A sudden loss of skills or abrupt change in behavior would have triggered action in parents who took their child to the doctor for sniffles and coughs. I note that once Mrs. Mooney found internet references that suggested E.L.M. might be autistic, she took E.L.M. to her primary care provider and sought referrals to specialists. Although E.L.M.'s autism diagnosis was delayed because she did not display sufficient social impairments required for the diagnosis, the concerning behaviors were reported and recorded. Had they actually arisen in closer proximity to the vaccinations in June 2003, I am confident that her parents would have reported them.

Mrs. Mooney testified that the evaluators did not accurately record the medical histories they provided. Tr. at 60-62. While medical records may contain errors, ⁵⁰ given the complete lack of any documentation of symptoms consistent with petitioners' contentions and the consistency of the information that is contained in the records, it is more likely that petitioners are simply mistaken in their recollections concerning when E.L.M. displayed the behaviors they now contend started following her June 2003 vaccinations. As I suggested in my factual ruling, I do not think petitioners are deliberately misleading this court. I am quite willing to accept that E.L.M. has displayed the behaviors described, but not that these behaviors occurred at the time claimed, or that, at least initially, they were of the intensity and severity described. Rather, petitioners have conflated the time frame for the concerning behaviors displayed at 20-24 months of age with the post-vaccinal period. A good example of this conflation is testimony about E.L.M. losing weight and dropping off the growth curve shortly after the

⁴⁸ For example, petitioners routinely reported that their concerns about E.L.M.'s speech arose between October and December 2003 (when she was 20 to 22 months). *See*, *e.g.*, Pet. Exs. 3, p. 1; 4, p. 1; and 5, p. 2. Additionally, providers did not diagnose E.L.M. with autism until late 2004 because although she had speech and language delay she did not display significant symptoms associated with the other diagnostic criteria for autism. Pet. Exs. 5, pp. 2-8; 13, p. 22; *see White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064 at *4-9 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (discussing the diagnostic criteria for autism spectrum disorders). Thirdly, although some of the evaluators reference E.L.M. screaming, it was typically associated with change in activities and not a continuous or constant behavior. Pet. Exs. 3, p. 1; 5, p. 4; 7, pp. 1-2.

⁴⁹ Mrs. Mooney wrote seven journal entries in the six months following E.L.M.'s June 5, 2003 vaccinations. Pet. Ex. 22 at 10-12. None describes the severe change in behaviors that petitioners contend occurred. *See supra* at pp. 11-12.

⁵⁰ See, e.g., Pet. Ex. 11, p. 84; see *also* Tr. at 80 (discussing inaccurate reference to E.L.M.'s 18 month vaccinations instead of to her 16 month vaccinations).

vaccinations. The failure to thrive diagnosis was actually recorded before E.L.M.'s first birthday. Pet. Ex. 13, pp. 24 (growth chart), 60 (computer records showing failure to thrive diagnosis on September 18, 2002).

Petitioners' allegations that E.L.M. had a continual lack of eye contact, poor social interaction, and a decreased or absent response to her environment are thoroughly refuted by the video records.⁵¹ I acknowledge that in some video clips E.L.M. is crying and unhappy or does not react or respond to the person filming. However, given the various instances on the recordings where she is not displaying the alleged changes and instead is engaged with others and reacting to her environment,⁵² it is clear that she did not experience a chronic encephalopathy following her June 5, 2003 DTaP vaccination. See § 100.3 (b)(2)(ii) ("Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event.").

V. Conclusion.

Petitioners have failed to demonstrate that E.L.M. suffered a Table encephalopathy as a result of her June 5, 2003 DTaP vaccination, and despite being given the opportunity to do so they have not put forth an allegation of, or proven, a causation-in-fact injury. Therefore, this case is dismissed for a failure to establish entitlement to compensation. The clerk shall enter judgment accordingly.

IT IS SO ORDERED.

<u>s/Denise K. Vowell</u> Denise K. Vowell

Chief Special Master

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⁵¹ Petitioners did not play any of the video records at the hearing. Instead, Mrs. Mooney walked the court through the 43 photographs filed as petitioners' exhibit 21. Tr. at 31-48; *see also* Tr. at 94-96 (testimony of Mr. Mooney regarding photographs 26-29 and 36-37). A significant portion of her testimony was devoted to noting how the photographs demonstrate E.L.M.'s lost of eye contact. The use of photographs to illustrate the presence or lack of eye contact is generally problematic because photographs do not capture what was going on outside the narrow focus of the camera lens. Photographs do not convey if there was a loud sound that may have caused a person to turn to the left, thus looking away from the camera at the moment the photo was taken. For example, based solely on photograph 15, one could conclude that E.L.M.'s older sister, F.M., has reduced eye contact because in the photograph E.L.M. is looking directly at the camera and F.M. is not. Pet. Ex. 21 at 15. On the other hand, videotapes are very helpful in establishing when certain behaviors arose, including reduced eye contact, because they enable the viewer to see and hear what was occurring at the moment the behavior or activity was captured on film

⁵² See *supra* at p. 9. I note there are also recordings from 2004 where E.L.M. is seen interacting with others and demonstrating normal behaviors. See, e.g, Pet. Ex. 23.2 at 47:00 (hosting an imaginary tea party on March 18, 2004), 51:58 (playing with musical toy on March 25, 2004), 41:39 (sharing crayons and coloring with F.M. on February 19, 2004), 53:19 (interacting with pet dog on April 8, 2004), and 1:10:30 (playing with Noah's Ark toy on September 17, 2004).